

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
Rudi D. NEIRINCKX



Application No. 09/584,978  
Confirmation No. 5707

Filed: June 2, 2000

For: TREATMENT OF PSORIASIS  
THROUGH  
DOWN-REGULATION OF THE  
EGF-RECEPTOR WITH  
TOPICALLY-APPLIED EGF

Group Art Unit: 1654

Examiner: Jeffrey E. RUSSEL

Atty. Docket No. 2502491-991110  
(formerly 44334)

Customer No.

**\*35928\***

**35928**

PATENT TRADEMARK OFFICE

**DECLARATION UNDER 37 C.F.R. 1.132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
**ATTN: Mail Stop AF**

Sir:

1. I, Rudi Neirickx, am the inventor of the above-captioned application.
2. I hold a Ph.D. in Chemistry with 20 years experience in drug development.
3. I have been in communication with organizations in the human psoriasis treatment field regarding my invention.
4. Because of the lack of a suitable human model, the companies that contacted me require human data. Following are representative quotes:

a. "To follow up with our previous correspondences and your recent message to \_\_\_\_\_ office, I confirm that we have reviewed the preliminary

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information that you have provided. It appears that without having access to the clinical data generated with the 7 patients included in Skintek clinical trial it is difficult for us to confirm our interest. Please send us the details of the clinical data of the 7 patients so that our clinical experts review them and we will let you know if it is appropriate to have a meeting."

b. "If you have any more in vivo data or patient data you could provide this would greatly assist me in evaluating your technology."

5. That conclusion is supported by the FASEB J. Jackson et al. publication of record, published seven years after Nanney et al., which establishes the state of the art in 1999 that there was no animal model for psoriasis.

6. That conclusion is confirmed in the last full paragraph of Casaco et al.

7. Thus, there is no way to predict that a proposed treatment of psoriasis will be successful without an actual clinical trial.

8. I hereby declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true, and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

9. Further Declarant sayeth not.

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Date

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Rudi Neirickx